Market exploration: surgical instrument sterilisation in austere environments

Summary

On behalf of the UK Ministry of Defence (MOD), the Defence and Security Accelerator (DASA) is considering the potential for a competition to identify the means to deliver Medical Device Decontamination Capabilities (MDDC) within Defence's highly mobile medical facilities, all of which are designed to operate and deliver healthcare in austere environments.

This exploration is to better understand the current market and to potentially identify alternative ways to deliver high standards of decontamination of packed surgical items, when logistics, mobility and time to establish a MDDC capability are limited. This information will provide us with the knowledge on what potential MDDC capabilities already exist, novel solutions in development and areas that potentially require further investment by MOD.

Please note that this request for information is not a commitment to subsequently launch a formal DASA competition.

Background

Due to the nature of the future operational environment, where forces will be highly mobile, operating at reach from large logistic hubs and where engineering support may be limited, alternative ways of delivering sterilisation of surgical instruments will be needed.

Defence operate and deploy a number of different medical treatment facilities, where the level of surgical procedures conducted varies from, damage control surgery up to primary and restorative surgery. In the future operating environment, medical treatment facilities will need to move frequently, be delivered to sites by means which cannot limit the pitch, roll or angle at which potential solutions might be exposed to prior to establishment. They will need to be able to operate after significant changes in altitude and temperature, whilst also being capable of being established and certified by user communities (nursing or operating department practitioners), rather than contracted specialists.

Current in-service systems rely on either wet heat to deliver sterilisation for its packed surgical kits. However, there may be solutions which exist where sterilisation may not even be required; this could include sterile 3D printing, use of chemicals or plasma sterilisation.

Essential requirements

- the ability to deliver sterilised instruments to surgical treatment teams in packaged and pre-prepared wrappings
- any system should be capable of being transited in temperatures of between -30°C to +55°C and relative humidity values could be up to 55%
- any system will be required to operate in potential operating ranges of 0°C to +40°C
- the cycle of effort should be based upon the ability to decontaminate a ‘set’ of surgical instruments at a rate of once per hour up to every three hours – with a rate not expecting to be above that of eight complete sets per day
- as a minimum, the standards of sterilisation must be aligned to a recognisable international standard
- identify any other requirements (such as a washer disinfector, water treatment, ultrasonic cleaner) required to deliver the effect
- any power requirements should be aligned with 240v 50/60 Hz AC single Phase
- the system shall be capable of sterilising a set of surgical instruments that can be packed into a container
- current containers range from between 425mm (L) x 190mm (W) x 85 to 180mm (H). However, this should not be seen as a limiting range.
- the system must not rely on plumbed or access to piped or pressurised water supplies

Desirable requirements

- complete solutions: fully integrated systems are ideal
- low personnel demands: deployable by 2 or 3 personnel, low training demand
- modifiable: power, configuration, logistic and engineering demands

What we want

Defence is particularly interested in turn-key, fully-integrated novel solutions which provide MDDC capabilities designed for deployment in austere/challenging environments.

What we don’t want

We are not interested in solutions that will require sophisticated infrastructure, logistical or engineering demands or the need for a high degree of training in order to deploy.

This is not a competition and therefore we are not asking for costed proposals at this stage. However, we have asked for your estimated cost range to inform future activities. This is a market engagement request for information exercise, and we do not commit to subsequently launch a formal DASA competition.

How to submit a Capability Submission Form

Responses to this market exploration must be submitted via the DASA submission service, for which you will be required to register.

There are 6 questions relating to your capability, where we are seeking to understand what and how much further development is required for a complete solution to all requirements, or whether a combination of separate solutions is required. The information you provide will assist in developing a statement of requirements for potential future activities. You will not be held to deliver to any of the timescales or cost estimates that you may give.

Submissions must be submitted by midday on Tuesday 8th December 2020.

Please only provide details of one product/capability per form. If you have a number of potential solutions, then please submit multiple forms. If you have any questions, then please email accelerator@dstl.gov.uk with 'MDDC' in the subject line.

How we use your information

Information you provide to us in a Capability Submission, that is not already available to us from other sources, will be handled in-confidence. By submitting a Capability Submission Form you are giving us permission to keep and use the information for our internal purposes, and to provide the information onwards, in-confidence, within UK Government. The Defence and Security Accelerator will not use or disclose the information for any other purpose, without first requesting permission to do so.

Local transport update: 2 November 2020

The Government and the Mayor of London have agreed a second extraordinary funding and financing package for Transport for London (TfL) for the period to 31 March 2021. It replaces the agreement signed in May. It will ensure the continued operation of public transport services in London and is proof of our commitment to supporting the capital and the transport network on which it depends.

As with the national rail network, the government will make up the revenue which TfL has lost due to the COVID pandemic over the period. The new package comprises a central funding scenario of £1 billion – made up of £905 million grant funding and £95 million borrowing – with flexibility for changing the grant payment in response to changing passenger demand.

Actual payments are likely to be greater than £1 billion because of the move to national COVID restrictions. TfL continues to need substantial support due to the significant fall in revenue caused by COVID-19. However, choices made in the preceding 4 years have made TfL less resilient to the impacts of the pandemic and this is why it's of vital importance that the Mayor brings forward plans to re-establish a trajectory to financial sustainability as soon as possible.

As well as the conditions in the package agreed in May, the new agreement, therefore, sets out further measures to put TfL on a sustainable financial footing as soon as possible.

Over the next 6 months, the Mayor will impose fare rises of Retail Price Index (RPI) plus 1 per cent on all modes from January 2021, maintain the central London congestion charge at the hours and level to which it was increased in June, maintain the withdrawal of 60-65 Pass and 66+ Freedom Pass concessions in the morning peak, and make a further £160 million in-year savings, additional to those already planned, with the exception of active travel, which will remain as in the first half of the year.

TfL will co-operate with a government-led review of driverless trains. The 2 government special representatives will continue to attend TfL board and panel meetings. A new government-led working-level oversight group will be created. By 11 January 2021, TfL will produce a single, comprehensive management plan with options as to how a trajectory to financial sustainability by 2023 can be achieved. Any grant from government to support London must be fair for UK taxpayers.

If the Mayor wishes Londoners to continue to benefit from travel concessions and/or other benefits above those typically available elsewhere in England, he and TfL have recognised that the costs of these additional benefits will not be met by the government and that they will meet these costs themselves, without recourse to additional borrowing, savings, service changes or deferrals.

TfL and the Mayor have proposed that this could be done by an increased council tax precept from April 2021. They will submit their proposals by 11 January 2021, alongside the fiscal sustainability plan. The government will take all steps necessary at the appropriate times to enable this proposal.

Extending the congestion charging zone to inner London has been ruled out by both the government and the Mayor. National travel concessions including free travel to school for those who qualify under the 1996 Education Act will continue to be funded by the government. The Freedom Pass for pensioners and the disabled will continue as now. It's not funded by TfL or the Mayor.

You can read the full agreement on the GOV.UK website.

36th Universal Periodic Review: UK statement on Belarus

Thank you Madam President.

The United Kingdom acknowledges Belarus' engagement in the UPR, but remains deeply concerned that systematic human rights violations continue in Belarus.

We condemn the arbitrary detentions, violence and intimidation against peaceful protestors, independent journalists and members of the opposition.

We recommend that Belarus:

1. Immediately lift restrictions on freedoms of association, peaceful assembly and expression, including on independent media and the Internet.

2. Release those arbitrarily detained, and investigate all allegations of torture or cruel, inhuman or degrading treatment or punishment, particularly related to people in detention.

3. Implement the recommendations in the OSCE Rapporteur's Report under the Moscow Mechanism.

Thank you.

Published 2 November 2020

Milestone 1 million Yellow Card report for suspected side effects in #MedSafetyWeek

Press release

The Yellow Card scheme is the UK's system for reporting suspected side effects to medicines and adverse events with medical devices run by the Medicines and Healthcare products Regulatory Agency (MHRA).

- Major milestone – 1 million Yellow Card reports since scheme started over 50 years ago
- Reporting suspected side effects helps to make medicines safer for everyone
- MHRA launches #MedSafetyWeek to further encourage people to report

The MHRA received its one millionth Yellow Card. This major milestone coincides with the launch of the 5th annual #MedSafetyWeek (2-8 November), which highlights the value of the Yellow Card scheme to the nation's health, and the importance of reporting suspected side effects from medicines. The MHRA has seen an increased rate of Yellow Card reports and would like to continue to encourage more reporting this #MedSafetyWeek.

Reporting helps to identify new side effects, as well as unexpected and serious safety problems. It also adds to existing information about known effects. By reporting, patients and the public can help the safe use of medicines for everyone. It helps the MHRA to take action, through effective regulation.

One recent positive change to medicines information for users involves a woman in the UK who has helped identify a newly recognised side effect from a blood pressure medication. While pregnant, Liz noticed some unusual side effects when taking her medicine and reported it to the MHRA using the Yellow Card scheme.

> Shortly after taking each dosage, I would feel an extreme burning sensation in my nipples which intensified over a period of about 20 minutes. It was agonising.
>
> At first, I didn't make the link between the tablets and the pain – I presumed it was just a pregnancy side effect. My doctor and other healthcare professionals weren't aware of it as a reported side effect for my medication.
>
> I decided to report my symptoms to Yellow Card because, however rare, I wanted to make sure anyone else experiencing it wouldn't feel alone.
>
> MHRA investigated my report alongside other reporting and clinical data and found that nipple pain was a symptom of Raynaud's phenomenon, a known side effect of this particular medicine.
>
> They worked with the manufacturers to improve the patient safety information – and the medicine now includes nipple pain as a possible side effect of Raynaud's phenomenon.
>
> It didn't take much time to do and I'm glad that anyone else experiencing this problem will now understand its probable cause. It's good to know I've been able to make a difference.

Liz recovered from the side effect she experienced.

Minister for Innovation Lord Bethell said:

> Everyone should have access to safe and effective medicines, without fear of unexpected side effects, and the news of the MHRA receiving their one millionth Yellow Card is a testament to how important this scheme truly is.

I urge everyone to report any side effects or other major concerns with their medicines through this vital scheme and ensure we all play our part in keeping the British public safe.

Mick Foy, Head of Pharmacovigilance Strategy of MHRA's Vigilance and Risk Management of Medicines Division, said:

Patient safety is our number one priority.

We want this campaign to encourage everyone to report suspected side effects from medicines and make more people aware of our Yellow Card scheme. This important milestone shows that every report counts and contributes to improving the safety of medicines for all patients.

Ends

Notes to Editor

1. The MHRA, who run the Yellow Card scheme, are responsible for protecting and improving the health of millions of people every day through the effective regulation of all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

2. Anyone can use the Yellow Card scheme to report suspected side effects of medicines, incidents involving medical devices, defective, fake medical products and safety concerns for e-cigarettes or their refill containers (e-liquids). Reports can be made on the Yellow Card website, via the mobile app from the Google Play Store or Apple App Store, via freephone (0800 731 6789, 9am to 5pm Monday to Friday) or by reporting an issue to their healthcare team who can file a report on their behalf. Patients are also advised to contact a healthcare professional if they are worried about their health. Yellow Card reporting for suspected side effects is also integrated into some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank and Ulysses).

3. The Yellow Card scheme is an early warning system for detecting medicines and patient safety issues. Many suspected side effects reported to spontaneous reporting systems, such as the Yellow Card scheme in the UK, are expected and listed in the product information. Data over a longer period and a larger database allows regulators to assess and look for patient safety trends and conduct robust signal detection. Thereby enhancing the detection of new, rare reactions,

interactions, medication errors where harm occurs, reactions associated with long term use of a medicine and to gain more information about the safe use of medicines e.g. in vulnerable populations. The Yellow Card scheme has identified many new safety issues that were unknown before being reported via a Yellow Card.

4. National medicines regulatory authorities from 73 countries across the globe and their stakeholders will be taking part in this international campaign led by Uppsala Monitoring Centre (UMC), a World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring. The campaign is supported by members of the Heads of Medicines Agencies (HMA) and the International Coalition of Medicines Regulatory Authorities (ICMRA). The #MedSafetyWeek 2020 project team consists of representatives from the following medicines regulators working collaboratively: the Medicines and Healthcare products Regulatory Agency (UK), the Food and Drugs Authority (Ghana), Pharmacy and Poisons Board (Kenya), Health Sciences Authority (Singapore), and the State Institute for Drug Control (Slovakia).

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CMA to examine if 'eco-friendly' claims are misleading

This new programme of work is a response to the growing number of products and services being marketed as environmentally friendly, as awareness of environmental issues increases. In 2019, UK consumers spent £41 billion a year on ethical goods and services – almost 4 times as much as people spent two decades ago.

Based on its own research and evidence from other enforcers, the Competition and Markets Authority (CMA) is concerned that this surge in demand for green products and services could incentivise some businesses to make misleading, vague or false claims about the sustainability or environmental impact of the things they sell.

Examples of misleading behaviour could include:

- exaggerating the positive environmental impact of a product or service
- using complex or jargon-heavy language
- implying that items are eco-friendly through packaging and logos when this is not true

As part of its work, the CMA will also consider whether failing to provide

all relevant information about the sustainability of a product or service – for example, whether it's highly polluting or non-recyclable – could mislead consumers and therefore break consumer law.

The CMA is looking across a wide range of sectors, although it is likely to focus on those industries where consumers appear most concerned about misleading claims, including textiles and fashion, travel and transport, and fast-moving consumer goods (food and beverages, beauty products and cleaning products).

The CMA wants to better understand the impact of green marketing on consumers, in line with the commitment made in its annual plan. The CMA is therefore calling on the public to have their say on what they expect from eco-friendly products, how often they come across green claims, and how these claims affect their purchasing decisions. The CMA is also consulting with charities, businesses and other organisations to get a clearer picture of the issues in this area.

Following these discussions, the CMA intends to publish guidance for businesses next Summer to help them support the transition to a low carbon economy without misleading consumers. At this early stage, the CMA has not reached a view as to whether or not consumer protection law has been broken. However, if it finds evidence that businesses are misleading consumers, then it will take appropriate action.

Andrea Coscelli, Chief Executive of the CMA, said:

> Increasing numbers of people are quite rightly concerned about the environment and want to play their part by being greener. Our role is to make sure that consumers can trust the claims they see on products for sale and don't fork out extra for items falsely presented as eco-friendly.
>
> We know that many businesses will be looking for ways to reduce their carbon footprint and we strongly support this, but the claims they make must not mislead consumers in the process. It's important that people can easily choose between those who are doing the right thing for the environment and those who are not, so that businesses genuinely investing in going green can be properly rewarded by their customers.

Although UK marketing practices will be the focus of the CMA's examination, the CMA is also taking a leading role in looking at green claims in a global context. Work will be carried out alongside the Dutch Authority for Consumers and Markets, as part of a project with ICPEN (the International Consumer Protection and Enforcement Network). From 9 to 20 November, the CMA will co-ordinate a 'sweep' of randomly selected websites with ICPEN members, with the aim of identifying the types of misleading green claims being made around the world.

All updates on the CMA's work in this area can be found on the misleading

environmental claims case page.

1. The key piece of consumer protection legislation relevant to the CMA's investigation is the Consumer Protection from Unfair Trading Regulations 2008 (CPRs). The CPRs contain a general prohibition against unfair commercial practices and specific prohibitions against misleading actions or misleading omissions.
2. Figures about consumer spending are taken from the Co-op's report 'Twenty Years of Ethical Consumerism'.
3. Read more about how the CMA is supporting the transition to a low carbon economy in its 2020/21 Annual Plan.
4. Businesses can shares their views about the CMA's 'green claims' work and other stakeholders (charities, government departments and consumer organisations) can share their views.

5. For more information about the ICPEN sweep, visit: https://icpen.org/

6. Media enquiries should be directed to press@cma.gov.uk or 020 3738 6460.